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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,608	02/21/2002	Darius M. Ameri	2004020-0001	7281
7590	03/11/2004			
John A. Hamilton, III Choate, Hall & Stewart 53 State Street Exchange Place Boston, MA 02109			EXAMINER	BUI, VY Q
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 03/11/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/079,608	AMERI, DARIUS M.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Vy Q. Bui	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 September 2002.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 20 recites the limitation "stylet assembly" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipate by DENNIS (US 5,853,392).

DENNIS (Figs. 1-2; col. 3, lines 63-67; col. 4, lines 58-66) discloses a guide needle 10 comprising tubular elongate member 11 having sharp bevel distal tip 12, axial bore 14, handle 15, sound indicator or whistle 32 as means for indicating insertion depth of the member 11, obturator 20/stylet 23 biased by spring 31 as means for preventing unintended puncturing by tip 12 as recited in the claims.

Claim 12 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DENNIS (US 5,853,392).

As mentioned above, DENNIS discloses the device as claimed and the pressure of an insufflating for activating whistle 32. Inherently, DENNIS discloses a method of insertion the guide needle as claimed. Alternatively, it would have been obvious to one of ordinary skill in the art to recognize that a physician can use DENNIS device in a manner as recited in the claim to place the DENNIS guide needle in a proper position according to his own judgment.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 3-5, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over DENNIS (US 5,853,392).

As to claims 3-4, DENNIS discloses substantially all structural limitations of the claimed invention, except for the gauge and length of the device. However, it would have been within level of one of ordinary skill in the art or obvious to one of ordinary skill in the art to size the DENNIS device as recited in the claims so as the device can be

used in different applications such as a larger size for use with an adult and a smaller size for use with a child.

As to claim 5, DENNIS discloses substantially all structural limitations of the claimed invention, except for visible gradations at measured intervals along member 11. However, it would have been obvious to one of ordinary skill in the art to provide visible gradations as claimed to DENNIS device because using visual gradations are well known in the art for indicating a penetration depth of a device.

As to claim 9, DENNIS discloses substantially all structural limitations of the claimed invention, except for a control mechanism on or near handle 15 for manually extending or retracting the stylet 23. It would have been an obvious matter of design choice to construct DENNIS device as recited in the claim because the control mechanism does not appear significantly improve the performance of DENNIS device and the invention would perform equally well without the control mechanism as recited in the claim.

As to claim 11, DENNIS discloses substantially all structural limitations of the claimed invention, except for a guard enveloping the member, handle and stylet assembly. It would have been obvious to one of ordinary skill in the art to provide a guard enveloping the member and handle and stylet assembly of the device before use so as one can guarantee that the device is safe during handling and remained sterilized for a surgical operation.

2. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over DENNIS (US 5,853,392) in view of RHAD et al. (US 6,663,592).

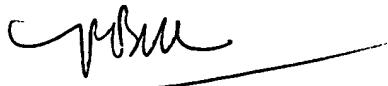
As to claims 6-7, DENNIS discloses substantially all structural limitations of the claimed invention, except for a pointer mechanism lockable to any visual gradation comprising a ring and means for locking the position of the ring at any visual gradation. RHAD (Figs. 9-10) shows ring 226 and lock means 270 lockable to recess 224 so that ring 226 can be properly locked to member 238. In view of DENNIS, it would have been obvious to one of ordinary skill in the art to provide a pointer lockable to any visual gradations on DENNIS member 11 comprising a ring similar to RHAD ring 226, a lock means similar to RHAD lock means 270 so as one can lock the pointer to any visible gradation along member 11 as recited in the claim.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



VQB  
March 3, 2004